

Notice of Allowability

Application No.

10/607,598

Examiner

Jegatheesan Seharaseyon, Ph.D

Applicant(s)

MARTIN ET AL.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/30/2007.
2. ☒ The allowed claim(s) is/are 1,2,7-15,17,18,20,29,30 and 35.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached:
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 1/24/2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud

DETAILED ACTION

1. This Office Action is in response to Applicant's arguments filed 1/30/2007.
Claims 1-21 and 29-34 were pending. Claims 1, 2, 5, 11-12, 15, 18, 29, 30, 32 and 33 are amended. Claims 3, 16, 31 and 34 are canceled. Claim 35 has been added. Claims 1, 2, 4-15, 17-21, 29, 30, 32, 33 and 35 are pending.
2. The declaration filed under 37 C. F. R. 1.132 has been fully considered.

Information Disclosure Statement

3. The information disclosure statement filed 1/24/2007 has been considered.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan A. Siegel on 3/1/07.

5. The application has been amended as follows:

In the claims

Please cancel claims 4-6, 19, 21, 32 and 33.

Please amend claims 1, 2, 7, 8, 9, 14, 15, 29, 30 and 35

1. (Currently Amended) A method for treating a subject with multiple sclerosis, comprising administering to the subject a therapeutically effective amount of daclizumab

Art Unit: 1647

~~an antibody that specifically binds p55 or p75 of an IL-2 receptor~~, in the absence of treatment with beta interferon, wherein the subject has failed to respond to previous treatment with beta interferon, thereby ameliorating a symptom of multiple sclerosis and treating the subject.

2. (Currently Amended) The method of claim 1, wherein daclizumab ~~the antibody~~ is administered intravenously.

7. (Currently Amended) The method of claim ~~[[4]]~~ 1, wherein ~~the antibody~~ daclizumab is administered at a dose of about 1 to about 3 milligrams per kilogram intravenously.

8. (Currently Amended) The method of claim ~~[[4]]~~ 1, wherein ~~the antibody~~ daclizumab is administered at a dose of about 1 per kilogram to about 2 milligrams per kilogram intravenously.

9. (Currently Amended) The method of claim ~~[[6]]~~ 1, wherein daclizumab ~~the antibody~~ is administered biweekly.

14. (Currently Amended) The method of claim 1, wherein the subject has secondary progressive multiple sclerosis.

15. (Currently Amended) The method of claim ~~[[4]]~~ 1, wherein daclizumab ~~the humanized monoclonal antibody~~ is administered at least biweekly for a period of at least two months, thereby treating the subject.

29. (Currently Amended) A method for treating a subject with multiple sclerosis, comprising selecting a subject with relapsing remitting multiple sclerosis who has been treated with interferon-beta and failed to respond to the interferon-beta treatment;

Art Unit: 1647

administering to the subject intravenously a therapeutically effective amount of daclizumab ~~a human antibody that specifically binds p55 of the interleukin-2 receptor,~~ wherein the subject is not treated with interferon- β , thereby ameliorating a symptom of multiple sclerosis and treating the subject.

30. (Currently Amended) The method of claim 29, wherein daclizumab ~~the antibody~~ is administered at least biweekly for a period of at least two months.

35. (Currently Amended) The method of claim 1, wherein daclizumab ~~the antibody that specifically binds p55 or p75 of the IL-2 receptor is administered~~ subcutaneously

REASONS FOR ALLOWANCE

6. The studies and results presented (including the declaration) document that treatment of the subject with multiple sclerosis using daclizumab alone (in the absence of interferon-beta) provides an unexpectedly superior results namely a complete absence of new lesions, and decrease in the total number of lesions in the brain. Thus, the showing of an unexpectedly superior result overcomes any *prima facie* case of obvious over Study of Zenapax in combination with Light et al.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Claims 1, 2, 7-15, 17, 18, 20 29, 30 and 35 are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 04/07

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud